*Form Approved: OMB No. 0910-0045. Expiration Date: April 30, 2001. See OMB Statement on Reverse.*

**DEPARTMENT OF HEALTH AND HUMANS SERVICES**
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

# DRUG PRODUCT LISTING

*(In accordance with Public Law 92-387)*

NAME AND ADDRESS OF FIRM

LABELING REVISON
CHANGE OF:
☐ RTE OF ADMIN ☐ INDICATION
☐ NAME / DOSE / STR / INGR
☐ OTHER *(Specify)*

**FOR FDA USE**

CONTROL NO. (1–5) | RECORD ID (6–11) | (12–15)

| SEC | S | U | PRODUCT TRADE NAME OR CATALOG NAME (20–83) | NATIONAL DRUG CODE: LABELER (84–89) | PRODUCT (90–93) |
|---|---|---|---|---|---|
| 01 | | | | | |

| FDA APPLICATION NO. (94–99) | REPORT DATE: MO (100–101) | DA (102–103) | YR (104–105) | TYPE RPRT (106) | TYPES OF BUSINESS (107–111) | OTHER *(Specify)* | PRODUCT TYPE (112–116) | OTHER *(Specify)* | BNDD (117) | LEGAL STATUS (118) | SCHED (119) | PROF USE (120) | PRODUCT DISCONTINUED (121–125) | OTHER *(Specify)* | BASIS OF CONCENTRATION: WHOLE NUMBERS (126–133) | DECIMAL (134–137) | UNIT (138–140) |
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| DOSAGE FORM (141–143) | ROUTES OF ADMINISTRATION: 1 (144–147) | 2 (148–151) | 3 (152–155) | OTH (156) | PT (157–158) | SEC (16–17) | S (18) | U (19) | SMPL (20) | PKG CODE (21–22) | PACKAGE SIZE (23–47) | PACKAGE TYPE (48–72) |
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| INITIAL MARKETING DATE: MO (159–160) | YEAR (161–164) | MOST RECENT MARKETING DATE: MO (165–166) | YEAR (167–170) | DISCONTINUED DATE: MO (171–172) | YEAR (173–176) |
|---|---|---|---|---|---|
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*NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1,000, or both (FDA&C Act, Section 303).*

| SEC (16–17) | S (18) | U (19) | TYPE (20) | PT (21–22) | ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC. (44–107) | FDA USE ONLY: INGREDIENT NO. (23–28) | AMOUNT: WHOLE NUMBER (29–36) | DECIMAL (37–40) | UNIT (41–43) |
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| SEC (16–17) | S (18) | U (19) | SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER (20–26) | ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT (27–66) | STATE (67–68) | FOREIGN COUNTRY (69–78) | NDC LABELER CODE (79–84) | SHORT NAME (85–99) |
|---|---|---|---|---|---|---|---|---|
| 07 | | | | | | | | |
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Food and Drug Administration
Information Management Team, HFD-095
5600 Fishers Lane
Rockville, MD 20857

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Food and Drug Administration
Information Management Team, HFD-095
5600 Fishers Lane
Rockville, MD 20857

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If using Federal Express, DHL or any special carrier to return this form, please use the following address:

(Please refer to the Drug Registration and Listing Booklet.)

When completing this form, please refer to the Drug Registration and Listing Instruction Booklet for assistance.
**PLEASE PRINT IN ENGLISH USING BLACK INK.**

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